REMARKS

Claims 48-64 and 73-76 are pending in this application. Applicants respectfully request reconsideration of this application.

Applicants acknowledge the courtesies extended to James M. Hanifin, Jr. during the telephone interview on June 2, 2004 with Examiner Isabella. The substance of the discussion during the interview is incorporated into the following remarks.

As indicated during the interview, Applicants again request an opportunity for counsel to discuss this application with the Examiner, SPE McDermott and the responsible SPRE prior to issuance of a Notice of Allowance in the event that the pending claims are found to be allowable and the Examiner concludes that there are no grounds for declaring an interference with U.S. Patent No. 5,304,187 (Green), as discussed below. SPE McDermott previously indicated that she was agreeable to such a discussion during a telephonic interview on November 13, 2003 with the undersigned.

Allowable Subject Matter

Applicants acknowledge the Examiner's finding that claims 49-59 would be allowable if rewritten in independent form to include all the limitations of the base claim and any intervening claims. Applicants have not rewritten these claims in independent form because they depend from claims that are believed to be allowable, as discussed below.

Claim Rejections - 35 U.S.C. §112

Claims 48, 60-64 and 73-76 stand rejected under 35 U.S.C. §112, first paragraph, on the basis that the written description of the specification defines the "loading and delivery" device as the combination of the main body and the cartridge and the claims recite only the main body of the combination. The Examiner contends that the specification does not support the invention as claimed. Applicants respectfully disagree.

The first paragraph of 35 U.S.C. §112 requires that the "specification shall contain a written description of the invention . . ." To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. MPEP

2163(I). It is well accepted that a satisfactory description may be in the claims or any portion of the originally filed application. MPEP 2163(I).

As discussed during the interview, the written description requirement is satisfied as one of ordinary skill in the art would readily conclude that Applicants had possession of the claimed inventions at least in view of the originally filed application. In this regard, the specification and drawings clearly describe a loading and delivery apparatus that comprises an elongated body having particular features as recited in claim 48. Moreover, as discussed during the interview, there is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. See MPEP 2163(I)(A). As discussed, the scope of claim 48 is commensurate with the scope of original claim 48. In this regard, original claim 48 did not require the loading and delivery apparatus to include either a cartridge or an introducer shaft. Independent claims 75 and 76 similarly do not require the loading and delivery apparatus to include either a cartridge or an introducer shaft. Thus, the specification clearly satisfies the written description requirement for the claimed inventions recited in the pending claims, including independent claims 48, 75 and 76, at least in view of the original claims. Accordingly, the rejection of the claims under §112, first paragraph, is improper and should be withdrawn.

As discussed during the interview, the specification does not "define" the loading and delivery device as the combination of the main body and the cartridge as asserted by the Examiner. Although the specification discloses an illustrative embodiment of a loading and delivery apparatus that includes a main body, a cartridge and an introducer shaft, this description alone does not require that the claimed invention be limited to each of these features. A claim that is broader than any particular embodiment shown in the patent specification satisfies §112, first paragraph, except in the rare instance when the specification explicitly limits the invention to a much narrower scope. See Cordis Corp. v. Medtronic Ave, Inc., 339 F.3d 1352, 1365 (Fed. Cir. 2003) (claim held valid: "A specification may, within the meaning of 35 U.S.C. §112 para. 1, contain a written description of a broadly claimed invention without describing all species that the claim encompasses.") (internal quotes omitted); Cooper Cameron Corp. v. Kvaerner Oilfield Products, Inc., 291 F.3d 1317, 1323 (Fed. Cir. 2002) (reversing finding of invalidity and concluding that a broad claim only fails the written description requirement if "the entirety of the specification clearly indicates that the invention is of a much narrower scope.") (emphasis

added). As discussed during the interview, the specification does not indicate that either the cartridge or the introducer shaft is an essential or critical feature of the claimed invention.

In the Office Action, the Examiner contends that the "specification discloses only one embodiment of the 'loading and delivery apparatus' and not 'an embodiment' of a plurality of embodiments". (Office Action, page 4). The Examiner also contends that the loading and delivery apparatus includes a main body 202, an introducer shaft 206 and a cartridge 210 according to the specification. *Id.* The Examiner further contends that the specification fails to disclose any other embodiments directed to alternative means for loading the mesh to the inserter. *Id.* The Examiner asserts that the specification is specific to workings of the combination of the cartridge and the inserter tool. *Id.* Thus, the Examiner concludes that the claims as presented are incomplete. *Id.*

As discussed during the interview, the disclosure of a single embodiment does not necessarily limit a claimed invention. See Golight, Inc. v. Wal-Mart Stores, Inc., 355 F.3d 1327, 1331 (Fed. Cir. 2004) ("An applicant is not necessarily required by 35 U.S.C. § 112, ¶ 1 to describe more embodiments than its preferred one, and we have outright rejected the notion that disclosure of a single embodiment necessarily limits the claims."); Lampi Corp. v. American Power Products, Inc., 228 F.3d 1365, 1378 (Fed. Cir. 2000) ("It is a familiar principle of patent law that a claim need not be limited to a preferred embodiment."). Thus, the fact that the specification may describe a single embodiment of a loading and delivery apparatus does not require that the claimed invention be limited to each of the features of the disclosed embodiment to satisfy the written description requirement.

In view of the foregoing, the specification satisfies the written description requirement for claims 48, 60-64 and 73-76, such that the rejection of these claims under §112, first paragraph, is improper and should be withdrawn.

Interference

The Examiner previously indicated that Interference No. 104,374 was vacated on the basis that the claims of the present application and the claims of U.S. Patent No. 5,304,187 (Green) fail in meeting the requirements for establishment of an interference. As indicated previously, the undersigned contacted the Examiner on April 15, 2003 to discuss this issue after receipt of the non-final Office Action mailed on January 28, 2003. At that time, the Examiner 772335 1.DOC

indicated that there was no interfering subject matter in view of the §112, second paragraph, rejections. Applicants assume that the Examiner takes the same position in view of the §112, first paragraph, rejections. However, as set forth above, these rejections are improper and should be withdrawn.

Without limiting Applicants' position, in any way whatsoever, it is again submitted that there appears to be interfering subject matter between claims 48, 59-62, 73 and 75-76 of the pending application and claims 25-30 of the Green patent. Applicants request consideration of the potential interference issues set forth in the Petition filed on May 25, 1994 in connection with application Serial No. 07/886,689 (parent application).

CONCLUSION

In view of the foregoing remarks, Applicants respectfully request reconsideration of the pending claims.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicants hereby request any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,

By: Domes M. Hanifin Ir. B

WOLF, GREENFIELD & SACKS, P.C.

600 Atlantic Avenue

Boston, Massachusetts 02210-2211

Telephone: (617) 720-3500

Date: June <u>3</u>, 2004